



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------|------------------------|
| 10/804,760 | 03/19/2004 | Meir S. Sacks | MSS 65055 | 7688 |
| 7590 03/31/2009 | | | | |
| Alan G. Towner Pietragallo, Bosick & Gordon One Oxford Centre, 38th Floor 301 Grant Street Pittsburgh, PA 15219 | | | EXAMINER VAKILL, ZOHREH | |
| | | | ART UNIT 1614 | PAPER NUMBER |
| | | | MAIL DATE 03/31/2009 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/804,760

Applicant(s)

SACKS ET AL.

Examiner

ZOHREH VAKILI

Art Unit

1614

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- _____ Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- _____ Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1 and 4-10 are presented for examination.

Applicant's Amendment filed December 24, 2008 has been received and entered into the present application. Claims 1 and 4-10 are pending and are herein examined on the merits.

Applicant's arguments, filed December 24, 2008 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112 (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. Applicant adds new limitations to the claims that raise the issue of new matter. New matter issues are raised when Applicant includes limitations in the claims that he/she clearly did not have possession of at the time of invention. The silence of the disclosure regarding **consisting essentially of** is not sufficient to now claim the exclusion of such steps because nowhere in the disclosure has Applicant discussed **consisting essentially of** in the context of the claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laruelle et al. (US Pat. No. 4472387) in view of Sandyk (US Pat. No. 5470846) and further in view of Castillo et al. (US Pat. No. 6264994 B1).

Laruelle et al. disclose a pharmaceutical composition suitable for increasing cerebral serotonin concentration, comprising a serotonin precursor and inosine and hypoxanthine (see abstract). Treatment consists of administering to a mammal having a lower than normal cerebral serotonin level an amount of a pharmaceutical composition of the present invention effective to increase the cerebral serotonin level. Daily dosages of 1 to 100 mg/kg are preferred (see col. 5, lines 8-22).

Sandyk teaches a method of treating neurological and mental disorders which are associated with and/or related pathogenetically to deficient serotonin neurotransmission (see abstract). Treatment of neurological and mental disorders which are associated with pathogenetically to deficient serotonin are Alzheimer's disease and Parkinson's disease. Neurological and mental disorders are treated by administering to such humans in need thereof an effective amount of a composition which increases serotonin transmission (col. 7, lines 44-50).

Castillo et al. teach that the invention relates to compositions and methods for treating Alzheimer's Disease and other amyloidoses and cognitive and mental effects thereof; more particularly, it relates to herbal compositions for intervention in

Alzheimer's disease and other amyloidoses and for remedies to cognitive and mental effects thereof (col. 1, lines 12-17). The pharmaceutical agent is selected from polyphenols and plants sterols (see col. 8, lines 13-16).

Castillo et al. further discloses that the composition of the invention will have enhanced function when function when taken together with one or more of the following antioxidants such as vitamin C or vitamin E (see col. 19, lines 62-65).

One skilled in the art would have been motivated to combine the teachings of the above references considering that it is generally prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of serotonin, inosine, hypoxanthine, and antioxidants to increase the uptake of serotonin in treating Alzheimer's disease. It would follow that the recited claims define prima facie obvious subject matter. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to have combined the teachings of the above references to formulate a method of treating Alzheimers' patients by increasing the serotonin composition uptake along with antioxidants such as polyphenols and Vitamin C.

Finally, one would have a reasonable expectation of success given that Laruelle et al., Sandyk, and Castillo et al. provide a detailed blueprint for treatment of Alzheimers' patients, and the steps of which are routine to one of ordinary skill in the art.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). "A consisting essentially of claim occupies a middle ground between closed claims that are written in a consisting of format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For art purposes, "the consisting essentially of" language in the claim is treated as "comprising" language and it is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of language." (See MPEP 2111.03)

Thus in the absence of evidence to the contrary, the invention of claims 1 and 4-10 would have been prima facie obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Response to Argument

The modified rejection addresses Applicant's remarks and arguments.

Applicant's remarks have been fully and carefully considered in their entirety, but fail to be persuasive.

Conclusion

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner 1614

March 16, 2008

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614